(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

September 10, 2013
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:10 am.

PRESIDING: Jody Allen, Chairman

MEMBERS PRESENT:
Ellen B. Shinaberry, Vice-Chairman
Crady R. Adams
David Kozera
Dinny Li
Empsy Munden
Robert M. Rhodes
Pratt P. Stelly
Rebecca Thornbury
Cynthia Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant
Erin Barrett, Assistant Attorney General- arrived 3:00 p.m.

QUORUM: With ten members present, a quorum was established.

APPROVAL OF AGENDA: Staff presented an addition to the agenda which was a handout of the draft set of minutes from the September 4, 2013 Special Conference Committee. The agenda was approved as amended.

APPROVAL OF MINUTES: The Board reviewed draft minutes for the June 18, 2013 (Public Hearing), June 18, 2013 (Full Board Meeting), June 18, 2013 (Panel Formal Hearing), June 21, 2013 (Informal Conference Committee), July 17, 2013 (Telephone Conference Call), July 24, 2013 (Informal Conference Committee), July 25, 2013 (Panel Formal Hearing), July 25, 2013 (Informal Conference Committee and Special Conference Committee), August 20, 2013 (Ad Hoc on Collaborative Practice Agreements), August 20, 2013 (Special Conference Committee and Informal Conference Committee), August 21, 2013 (Telephone Conference Call), and September 4, 2013 (Special Conference Committee).

MOTION: **The Board voted unanimously to approve the minutes as presented. (motion by Stelly, second by Warriner)**

PUBLIC COMMENTS:

The Board received comments from two individuals. Tim Musselman, Executive Director, Virginia Pharmacists Association (VPhA), stated that the VPhA had questions regarding Guidance Document 110-36. He requested that the Board reconvene the ad hoc committee for further consideration of the guidance. He then introduced Loyd V. Allen, Jr., Ph.D, R.Ph., Editor-in-Chief for the *International Journal of Pharmaceutical Compounding* and *Remington: The Science and Practice of Pharmacy*. Dr. Allen briefly described his experience working as a volunteer member with the U.S. Pharmacopeial (USP) Convention and with the subject of sterile compounding. He prefaced that his comments were his own and not representative of the USP. He provided a handout (Attachment 1) which summarized his concerns with three of the numbered items within Guidance Document 110-36. He stated that USP chapters, such as Chapter <71>, were originally written for manufacturing with later standards written for pharmacy compounding. He is in the process of discerning which chapters he believes apply to manufacturing verses pharmacy compounding; he believes the numbered items referenced in his handout need further clarification. Ms. Allen thanked Mr. Musselman and Dr. Allen for their comments.

DHP DIRECTOR'S REPORT:

Dianne Reynolds-Cane, M.D., Director of the Department of Health Professions (DHP), was unable to attend the meeting due to a scheduling conflict. Arne Owens, Chief Deputy Director, DHP, presented the Director's report on her behalf. Mr. Owens reported that the state plan to reduce prescription drug abuse was submitted to the National Governors Association (NGA) on August 30, 2013. The plan consists of various suggestions and ideas to assist in the reduction of prescription drug abuse. Mr. Owens stated that DHP hosted the NGA Prescription Drug Abuse Policy Reduction meeting on March 25, 2013, and was one of the several state agencies that participated.

A request was made by staff to modify the agenda to include the Regulation Committee recommendation from the meeting that was held on September 9, 2013, regarding 18VAC 110-20-500 concerning emergency medical services (EMS) agencies.

MOTION:

The Board voted unanimously to modify the agenda to include the Regulation Committee recommendation regarding 18VAC 110-20-500 concerning emergency medical services agencies. (motion by Warriner, second by Thornbury)

REGULATIONS:

Ms. Yeatts highlighted certain regulatory activities as included on the update on page 37 of the agenda packet. The request for an extension of the emergency regulations for continuous quality improvement programs (CQI) is currently at the Governor's office. If approved, this will extend the emergency regulations until April 1, 2014. The change to run-dry requirements for automated counting devices was fast-tracked and has been in effect since August 2, 2013. The regulatory reform changes were also fast-tracked, and will become effective on September 26, 2013. The exempt regulatory action for the administration of drugs by emergency

medical services personnel become effective September 25, 2013.

FINAL ADOPTION OF PROPOSED AMENDMENTS FOR AUTOMATED DISPENSING DEVICES AND ON-HOLD PRESCRIPTIONS:

Ms. Yeatts reviewed the proposed amendments along with public comment received regarding the regulations for automated dispensing devices. A comment received from John Lubkowski suggested an amendment to section C2 of 18 VAC 110-20-490 to allow a discrepancy to be reported to the pharmacist-in-charge or his designee. Ms. Yeatts stated that the Board could consider making additional changes to the regulations per the public comment or adopt as presented. Several board members explained the importance of ensuring that the PIC is immediately informed of a discrepancy and did not believe it was appropriate to delegate another individual to receive this information.

MOTION:

The Board voted unanimously to not include the suggested language to allow a discrepancy to be reported to the designee of the pharmacist-in-charge and to leave the language as written. (motion by Adams, second by Rhodes)

MOTION:

The Board voted unanimously to adopt the final regulation 18 VAC 110-20-490 for automated dispensing devices as presented. (motion by Warriner, second by Kozera)

Ms. Yeatts reviewed the proposed amendments along with public comment received regarding the regulations for on-hold prescriptions.

MOTION:

The Board voted unanimously to adopt the final regulations for on-hold prescriptions as presented. (motion Rhodes, second by Kozera)

ADOPTION OF PROPOSED AMENDMENTS TO REGULATIONS GOVERNING COLLABORATIVE PRACTICE AGREEMENTS:

An ad hoc committee of the Boards of Pharmacy and Medicine met on August 20, 2013, to discuss possible amendments to the regulations governing collaborative practice agreements as a result of statutory changes from the passing of HB 1501. Ms. Yeatts explained that the committee recommended the adoption of the proposed amendments with the exception of 18 VAC 110-40-40 if counsel later indicated that the added language would not qualify as an exempt action. Ms. Yeatts reported that counsel did not believe the proposed added language in 18 VAC 110-40-40 conformed with exempt regulatory action requirements. The Board concluded that the suggested language in 18 VAC 110-40-40 was not necessary.

MOTION:

The Board voted unanimously to adopt the proposed exempt regulatory amendments to 18 VAC 110-40-10 and 18 VAC 110-40-20 regarding collaborative practice agreements as recommended by the ad hoc committee. (motion by Warriner, second by Shinaberry)

ADOPTION OF PROPOSED AMENDMENTS TO REGULATIONS FOR EMERGENCY MEDICAL SERVICES AGENCIES (EMS)

The Regulation Committee met on September 9, 2013, to discuss possible amendments to regulation 18 VAC 110-20-500 concerning the licensed emergency medical services (EMS) agencies program. It was the recommendation of the committee that the Board adopt the amended regulations as a fast-track regulatory action. It was recommended that the

PROGRAMS:

committee's proposed language in new section A 4 of 18 VAC 110-20-500 be changed from "perform an inventory of" to "reconcile the" and change the subsequent term "inventory" to "reconciliation".

MOTION:

The Board voted unanimously to adopt the proposed fast-track regulatory amendments of 18 VAC 110-20-500 regarding emergency medical services (EMS) agencies programs as recommended by the Regulation Committee and amended by the Board. (motion by Munden, second by Warriner)

SANCTIONING REFERENCE POINTS RESULTS FOR PHARMACY TECHNICIANS:

Neal Kauder and Kim Small with Visual Research, Inc., reviewed the sanctioning reference points (SRP) results for pharmacy technicians and presented a proposed worksheet to assist the Board during informal conference deliberations of pharmacy technicians. The worksheet is intended to be used in an analogous manner as the worksheet for pharmacists that the Board has used for several years. The goal for its use is to aid the board in determining appropriate disciplinary action in a consistent manner. Mr. Kauder stated that their review indicated there is not as much variability in case decisions for pharmacy technicians. The Board discussed the worksheet and made several changes by correcting a typo and removing language which did not pertain to pharmacy technicians. Mr. Kauder indicated he will provide staff with the final version reflecting the Board's amendments which can be posted online.

MOTION:

The Board voted unanimously to accept the Sanctioning Reference Points Worksheet for Pharmacy Technicians as amended. (motion by Kozera, second by Adams)

ADOPTION OF AMENDED BYLAWS, GUIDANCE DOCUMENT 110-12:

The Board reviewed staff's suggestions for amending the bylaws in Guidance Document 110-12 as presented on page 68-71. Ms. Juran explained that the suggestions reflect the advice received in recent years from psychometricians responsible for assisting the Board in the development of the drug law examination and pharmacy technician examination, as well as agency policy for the issuance and consideration of a request for proposal (RFP). The Board made the following additional amendments: changed references to "Examination Committee" throughout the document to "Examination Administrator Selection Committee"; and, removed "and robotic pharmacy systems" in A 5 since the allowance to use robotic pharmacy systems is now in Board regulation and is no longer considered by the Pilot Committee.

MOTION:

The Board voted unanimously to adopt the amended bylaws in Guidance Document 110-12 as presented and amended. (motion by Warriner, second by Adams)

UPDATE ON 2012 PHARMACIST AND PHARMACY TECHNICIAN WORKFORCE SURVEYS:

Justin Crowe, Research Analyst for the Board of Health Professions, presented to the Board the 2012 results of the Workforce Survey for pharmacists and pharmacy technicians performed during the last renewal period in December 2012. Currently, twenty-three health professions are being surveyed by the Healthcare Workforce Data Center and a standard

template is being utilized that was established by a past committee. A goal is to streamline collected data so it is comparable across professions. Mr. Crowe reviewed the handouts with the Board and stated that comments may be received until September 25, 2013.

STAFF REQUEST TO CONVENE AD HOC INSPECTION COMMITTEE TO REVIEW GUIDANCE DOCUMENT 110-9 AND DEVELOP SIMILAR GUIDANCE FOR INSPECTIONS OF PHYSICIAN SELLING DRUGS:

Staff indicated that the routine pharmacy inspection process has been in use for three years and that it may be an appropriate time to thoroughly review Guidance Document 110-9 regarding suggested monetary penalties resulting from routine pharmacy inspections. Additionally, staff suggested that the Board consider developing similar guidance for inspections of physician selling drugs locations as a means of expediting the possible disciplinary action resulting from the increased number of physicians licensed to sell drugs.

MOTION:

The Board voted unanimously to convene the ad hoc committee to review Guidance Document 110-9 and consider the development of similar guidance for the routine inspections of physicians licensed to sell drugs. (motion Rhodes, second Kozera)

BOARD MEMBER REQUEST TO DISCUSS POSSIBLE DISCIPLINARY ACTION AGAINST PICS FOLLOWING DOCUMENTED LOSS OF CONTROLLED SUBSTANCES:

Mr. Adams distributed a handout (Attachment 2) that supported his concerns regarding the documented losses of controlled substances within a pharmacy and that the pharmacist-in-charge (PIC) should be held accountable for that loss. Mr. Adams stated that during his research, he discovered that in the first six months of the year 2013, only nine disciplinary actions, resulting from drug losses, were taken against a PIC. The document outlined sections of law and regulation identified by Mr. Adams which he stated supports the pharmacist's responsibility to appropriately secure controlled substances.

MOTION:

The pharmacist-in-charge (PIC) of a pharmacy that experiences either diversion or theft of Schedule II-VI drugs exceeding 100 oral tablets, or 100 usual oral liquid doses, or 25 ampules or vials shall be in violation of:

1. **18 VAC 110-20-25(6) Unprofessional Conduct: Failure to maintain adequate safe guards against diversion of controlled substances and,**
2. **Section 54.1-3434: Failure to provide safeguards against diversion of all controlled substances and,**
3. **18VAC 110-20-110(B) Pharmacy Permits: Failure to control all aspects of the practice of pharmacy and,**
4. **Section 54.1-3432: Failure to supervise the pharmacy and its personnel. The PIC shall be fined a minimum of $250 up to $5,000 and reprimanded. (motion by Adams, second by Stelly, 8 opposed, motion defeated)**

MOTION:

The Board voted unanimously to refer Mr. Adam's concerns for drug diversion and PIC accountability to the Regulation Committee for further research and to determine the best course of action. (motion by Stelly, second by Rhodes)

SCHEDULING OF DATES FOR THE 2014 FULL BOARD MEETINGS:

Ms. Juran presented available dates for the upcoming 2014 full board meetings. The Board unanimously agreed on the following dates: March 26, 2014; June 4, 2014; September 9, 2014; and December 9, 2014.

- Chairman's Report:

Ms. Allen reported that members to the standing committees for 2013-2014 have been appointed. Ms. Reiniers-Day will have the informal conference committee dates to those members within the next two weeks. Ms. Allen also reported that Ms. Warriner, Ms. Juran and herself have been appointed to taskforces of the National Association of Boards of Pharmacy (NABP) and will be participating in the near future.

- Report on Board of Health Professions:

Mr. Rhodes gave an update regarding previous and upcoming meetings with the Board of Health Professions. He stated that the last meeting was cancelled, but a review of older documents is planned for next year.

- Report on Licensure Program:

Mr. Johnson reported that the Board issued 1,425 licenses and registrations for the period of June 1, 2013 through August 31, 2013, including 454 pharmacists, 109 pharmacy interns, and 697 pharmacy technicians. Inspectors conducted 432 facility inspections including 233 routine inspections of pharmacies: 74 resulted in no deficiency, 57 with deficiencies, and 102 with deficiencies and a consent order. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies. Mr. Johnson reported that since April 1, 2013, pharmacy inspectors have identified that 95 (49%) of 193 pharmacies inspected were not compliant with the emergency regulations for continuous quality improvement programs. The most frequently occurring area of noncompliance was failure to indicate a zero report when no dispensing errors occurred within the past 30 days. Mr. Johnson reported that there are 138 open cases involving inspection deficiencies.

- Report on Disciplinary Program:

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of September 28, 2012; March 8, 2013; June 14, 2013; and September 9, 2013. For the final date, open cases are two at the entry stage; 59 at the investigation stage; 74 at the probable cause stage; 18 at the administrative proceedings division stage; 11 at the informal stage; six at the formal stage; and 145 at the pending closure stage.

- Executive Director's Report:

Ms. Juran reported that the e-newsletter was published at the beginning of August. It is available online and was sent via email to the pharmacists, pharmacy technicians, pharmacy interns, and pharmacies which have provided an email address to the Board. Ms. Juran also stated that she attended the Virginia Pharmacists Association (VPhA) meeting in Virginia Beach on July 30, 2013 and gave a law update on behalf of the Board. Mr. Johnson will be giving a law update at the upcoming Virginia Society of Health-System Pharmacists (VSHP) meeting in October. Ms. Juran requested travel authorization to attend the NABP/AACP District meeting in Maine which is being held October 17th through October 19th. A travel request was submitted and approved for the NABP Interactive Executive Officer Forum being held in Chicago, September 24th through

September 25th. Ms. Juran stated that NABP was covering all expenses and that she will be participating on a panel to discuss a blueprint to address compounding issues. Additionally, Ms. Juran received a $1,500.00 travel grant to attend the NASCSA meeting in Kansas City this October. Ralph Orr, Director of the Prescription Monitoring Program, will also be attending and is running for President. Ms. Juran is awaiting approval for this trip. The Virginia Prescription Monitoring Program (VPMP) is now interoperable with Tennessee which is Virginia's first border state to participate in the interoperability. A tentative stakeholder meeting has been set for either October 7th or 8th for the Department of Behavioral Health and Developmental Services naloxone project "REVIVE". NABP will subsidize the cost of the recently hired inspector, Timothy Reilly, to attend the compounding training in Chicago this October. NABP will also hold an Interactive Compliance Officer Forum this December and DHP intends to submit a travel request for a pharmacy inspector to attend. Ms. Juran stated that there are a couple possible dates for the upcoming 2014 NABP/AACP District I and II meeting that will be hosted by Virginia. Ms. Juran and Ms. Allen have been discussing with the four schools of pharmacy the option of hosting the meeting in Williamsburg. Ms. Juran and Ms. Allen will visit The Williamsburg Lodge in Colonial Williamsburg on September 13th for a tour.

NEW BUSINESS:

There was no new business.

CONSIDERATION OF CONSENT ORDERS:

MOTION FOR CLOSED MEETING:

The Board voted unanimously to enter into a closed meeting pursuant to § 2.2-3711(A) (27) of the Code of Virginia for the purpose of deliberation to reach a decision regarding a Consent Order. Additionally, it was moved that Caroline Juran, Cathy Reiniers-Day, Sammy Johnson and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (motion by Shinaberry, second by Kozera)

MOTION TO CERTIFY THE PURPOSE OF THE CLOSED MEETING:

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for a closed meeting were heard, discussed, or considered during the closed session just concluded. (motion by Shinaberry, second by Kozera)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Jennifer Wild Hoerrner, Pharmacist (motion by Warriner, second by Shinaberry)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Diana Rachel Jensen, Pharmacy Technician (motion by Warriner, second by Shinaberry)

FORMAL HEARING:

DAVID A. SHIMP
Pharmacist
License Number:
0202-209023

A formal hearing held in the matter of David A. Shimp to discuss his petition for reinstatement of his pharmacist license that was mandatorily suspended on November 16, 2012, and allegations that he may have violated certain laws or regulations governing the practice of pharmacy in Virginia.

Erin L. Barrett, Assistant Attorney General, was present as legal counsel for the Board. James E. Schliessmann, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist. Mr. Shimp appeared and was represented by Joel M. McCray, Esquire.

Patricia Sheehan, DHP Senior Investigator, testified on behalf of the Commonwealth.

David A. Shimp testified on his own behalf.

Closed Meeting:

Ms. Shinaberry moved and the Board voted unanimously, to enter into a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of David A. Shimp. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran and Erin L. Barrett attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation

Reconvene:

Ms. Shinaberry moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

Ms. Stelly moved, and the Board voted unanimously, to accept the Findings of Fact and Conclusions of Law as proposed by Mr.Schliessmann, amended by the Board and read by Ms. Barrett..

Ms. Stelly moved, and the Board voted unanimously, that Mr. Shimp's petition for the reinstatement of his pharmacist license be approved with Mr. Shimp providing the Board with evidence of five (5) additional continuing pharmacy education hours.

ADJOURN:

With all business concluded, the Board adjourned at 4:30 p.m.

Jody H. Allen, Chairman

Date: _____

Caroline D. Juran, Executive Director

Date: _____

Attachment 1

Virginia Board of Pharmacy
COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

Of the 34 items listed, I am in agreement with the majority but have a few comments on the following (The numbers refer to the items phrased as numbered questions). I need to state that this is my personal response as I am acting as an individual and not a representative of the USP. I will provide documentation as appropriate in my responses.

2. Does the law require compliance only with Chapter <797>?

Response: The explanation is correct. However, one must keep in mind that most of the USP General Chapters were written for the pharmaceutical manufacturing industry, not for pharmaceutical compounding. Most of the chapters were written prior to the resurgence of pharmaceutical compounding so the terminology relates to manufacturing. However, we are now in the situation where we are trying to apply standards written for large scale manufacturers to small scale compounders. It will take time to get these chapters focused on the correct entities with reasonable standards for each.

4. Is it appropriate to assign a BUD of 90 days in the absence of sterility testing if there is literature indicating the stability of the drug is assured for 90 days.

Response: Extended BUDs can be used in the absence of direct sterility testing as follows: Note the "program of sterility testing" statement below and the reference from <797> back to <795> regarding BUDs.

<795> PHARMACEUTICAL COMPOUNDING—NONSTERILE PREPARATIONS
STABILITY CRITERIA AND BEYOND-USE DATING
General Guidelines for Assigning Beyond-Use Dates

"In the absence of stability information that is applicable to a specific drug and preparation, the following table presents maximum BUDs recommended for (1) Nonsterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature, unless otherwise indicated; and for (2) sterile preparations for which a program of sterility testing is in place."

<797> STORAGE AND BEYOND-USE DATING
Determining Beyond-Use Dates

"...BUDS for CSPs that lack justification from either appropriate literature sources or by direct testing evidence shall be assigned as described in *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding-Nonsterile Preparations <795>*."

6. How may a hospital pharmacy "batch-producing" limited quantity of CSPs for IN-HOUSE use extend the BUD past the default dating in Chapter <797>?

Response: If high risk batches of 25 or more are compounded, they must pass the sterility test. Batches less than 25 fall in the response to item #4 above.

FINISHED PREPARATION RELEASE CHECKS AND TESTS
Sterility Testing

"All high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or in multiple-dose vials (MDVs) for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test (see Sterility Tests <71>) before they are dispensed or administered."

16. What concepts, at a minimum, should be taken into consideration when performing sterility testing of CSPs? *The sample size used for testing must comply with USP Chapter <71>, tables 2 and 3.

Response: The requirements to meet USP <71> Sterility Tests do not work unless larger quantities of preparation are compounded. For example:

<71> STERILITY TESTS
TEST FOR STERILITY OF THE PRODUCT TO BE EXAMINED
Number of Articles to be Tested

"Unless otherwise specified elsewhere in this chapter or in the individual monograph, test the number of articles specified in Table 3."

Table 3 for Parenteral Preparations includes the following:

Not more than 100 containers.	Test 10% or 4 containers, whichever is the greater.

Comment: In USP <71>, it appears that the minimum number required for testing is 4 containers, unless the volume in each is insufficient for the tests where the number will be increased to 8. If one is compounding less than 4 vials, it does not meet the requirements of this chapter. It is impractical in many cases to prepare additional vials to bring the number up to the minimum required for this chapter. For example, it is not feasible to prepare 5 vials so one can be dispensed and four can be used for sterility testing. One must remember that most of the chapters in the USP General Chapters were designed, developed and written for the pharmaceutical industry, where large volumes are prepared, not for compounding where only a few may be prepared. In addition, many of these CSPs are quite expensive and this prohibits compounding extra units. Also, as mentioned above, I don't know of any hospitals that would compound 5 intravenous admixtures so they could send four for sterility testing and one for the patient. We are in an awkward time when compounding has rapidly grown but many try to apply USP chapters to compounding pharmacy that have been written over the past 30-40 years for the pharmaceutical industry.

Loyd V. Allen, Jr., Ph.D., R.Ph.
Editor-in-Chief
International Journal of Pharmaceutical Compounding
Remington: The Science and Practice of Pharmacy
June 24, 2013

Attachment 2

BOP Presentation Sept 10, 2013

Motion: The pharmacist-in-charge (PIC) of the pharmacy that experiences either diversion or theft of Schedule II-VI drugs exceeding 100 oral tablets, or 100 usual oral liquid doses, or 25 ampules or vials shall be in violation of:
1. 18VAC 110-20-25 (6) Unprofessional Conduct: Failure to maintain adequate safe guards against diversion of controlled substances and,
2. Section 54.1-3434: Failure to provide safeguards against diversion of all controlled substances and,
3. 18VAC 110-20-110 (B) Pharmacy Permits: Failure to control all aspects of the practice of pharmacy and,
4. Section 54.1-3432: failure to supervise the pharmacy and it's personnel.
The pharmacist-in-charge shall be fined a minimum of $250 up to $5000 and reprimanded.

Authority:

54.1-3307 A/3
Page 49 "The Board's regulations shall include criteria for... Controls and safeguards against diversion of drugs"

2013 Experience:
Based on available on-line data for the first six months of 2013 the Board of Pharmacy took action against 9 pharmacists/technicians documenting the theft/diversion of over 13,000 doses of Schedule II-V drugs.

AT Least

Pharmacy and Drug Control Act Section 54.1

-3300/Page 44 Definitions

"Practice of Pharmacy":	Proper and safe storage and distribution of drugs.
"Supervision":	Direction and Control by a pharmacist of the activities of a technician.
--3307 A/3 Page 49	"The Board's regulations shall include criteria for... Controls and safeguards against diversion of drugs..."
--3404/E Page 66	"Whenever any registrant or licensee discovers a theft of any unusual loss of any controlled substance he shall immediately report theft/loss to the Board."
----3434 /page 88	"...The pharmacist in charge assumes full responsibility for the legal operation of the pharmacy"

(and) "The pharmacist to whom the permit is issued shall provide safeguards against diversion of all controlled substances."

Regulations Governing the Practice of Pharmacy 18 VAC

110-20-25 (6) (page 9)	Unprofessional Conduct is: Failing to maintain adequate safeguards against diversion of controlled substances.
110-20-110 (B) (page 18)	"The pharmacist in charge or pharmacist on duty shall control all aspects of the practice of pharmacy"*****
110-20-190 (A/1) (page 25)	"The prescription department enclosure.....shall be constructed to protect prescription drugs....from pilferage at all times...."
110-20-240 (A/1) (page 28)	"Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs....and reconciled at least monthly."
110-20-440 (A) (page 48)	"The PIC in a hospital pharmacy shall be responsible for security of all drugs...."
110-20-555 (12) (page 60)	"The PIC of the pharmacy providing services to nursing homes... is accountable for security of all drugs maintained in the automated drug dispensing system..."
110-20-570 (B) (page 61)	"Drugs maintained in infirmaries/first aid rooms...shall be secured in a locked storage area..."
110-20-580 (4) (page 62)	"Drugs maintained in humane society/animal shelter shall be stored in a secure, locked place...."
110-20-700 (A) (page 67)	"The supervising practitioner shall establish procedures for.....(drug) security..."

==========

Guidance Document

110-27 PIC Responsibilities
Opening/closing inventory and change of PIC inventory
Report theft and any unusual loss of drugs.

110-5 Theft or Loss of Drugs
Complete DEA-106 form.